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EXAMINER	
GOTTSCHALK, MARTIN A	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/054,706	ALEMI ET AL.	
	Examiner	Art Unit	
	MARTIN A. GOTTSCHALK	3696	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. Claims 1-8 are pending. Claims 1 and 7 remain unamended. Claims 2-6 and 8 are amended to correct informalities. Since the claims are substantially unamended, the rejections from the previous Office Action are reproduced here only for the convenience of the reader.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/19/2007 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seare et al (US Pat# 5,557,514, hereinafter Seare) in view of Ziegele (PG Pub# US 2005/0125257, hereinafter Ziegele), and further in view of Lockwood (US Pat# 5,706,441, hereinafter Lockwood).

A. As per claim 1, Seare discloses an episode classification system including:

a. a multitude of diagnosis records (Seare: col 21, lns 10-19), each of said diagnosis records including:

i. diagnoses information (Seare: col 22, lns 14-27, e.g. “claim ID”);

ii. time of diagnoses information (Seare: col 22, lns 14-27, e.g. “claim ID”);

and

iii. patient information (Seare: col 22, lns 14-27);

b. a patient grouper for generating at least one patient group, each patient group generated by grouping patient records having similar patient information (Seare: Seare: col 24, lns 18-21, i.e. sorting by “index code”);

c. a diagnosis grouper for generating at least one diagnosis group from a patient group, each diagnosis group generated by grouping patient records from a patient group that have similar diagnosis information (Seare: col 24, lns 21-26, i.e. sorting on “qualifying ICD codes”);

d. an episode analyzer including:

ii. a episode grouper for grouping diagnosis records determined to belong to a single episode (Seare: Figs 2-5, and 12; col 23, section titled “Determination of Episode of Care”).

Seare fails to disclose item d-i, however this feature is disclosed by Ziegele, who teaches

i. a probability analyzer for performing probability calculations, each of said probability calculations capable of generating a probability value using at least

two of said multitude of diagnosis records as input entries, said probability value representing the probability that said input entries belong to a single episode (Ziegele: Fig 1; [0014] - [0016]);

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the teachings of Ziegele into the system of Seare with the motivation of maintaining updated relationships between diagnostic information records and actual and potential treatment modalities relevant to the diagnosis (Ziegele: [0010]).

Seare further fails to disclose item d-iii, however this feature is disclosed by Lockwood, who teaches

iii. a severity analyzer for performing episode severity calculations, each of said episode severity calculations capable of generating an episode severity value (Lockwood: col 4, lns 46-61).

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teachings of Lockwood into the system taught by Seare with the motivation of accurately differentiating levels of case complexity handled by different categories of healthcare providers (Lockwood: col 3, lns 43-53).

In subsequent claims combining the teachings of Seare, Lockwood, and Ziegele, the same motivation is applied as above, will not be repeated, and is incorporated therein.

B. As per claims 2-4, Seare discloses an episode classification system according to claim 1 wherein at least one of said diagnosis records is

(claim 2) an anchor diagnosis record (Seare: col 22, lns 49-52, reads on "date of service from");

(claim 3) a trigger diagnosis record (Seare col 8, ln 50 to col 9, ln 47, note the triggering effect of the Index table which the Examiner considers to be a type of trigger diagnosis record);

(claim 4) stopping point diagnosis record (Seare: col 22, lns 49-52, reads on "date of service to").

C. As per claim 5, Seare discloses an episode classification system according to claim 1 wherein said

calculation:

b. is a function of:

i. a similarity value, said similarity value representing the similarity between said pair of diagnostic records (Seare: e.g. an index code represents a similarity value, col 7, lns 35-64);

and

ii. a time between diagnosis value, said time between diagnosis value representing the time between said pair of diagnostic records (Seare: col 24, ln 60 to col 25 ln 26).

Seare discloses operating on one or more records but fails to disclose operating specifically on a pair of records. However this feature is well known in the art as evidenced by the teachings of Ziegele who teaches a probability calculation which

a. operates on a pair of diagnosis records (Ziegele: [0079]-[0080]).

D. As per claim 6, Seare teaches the similarity value as per the previous claim, but fails to explicitly disclose the rest of the claim, however these features are taught by Ziegele who teaches the episode classification system according to claim 5 wherein said probability calculation includes

a probability numerator divided by a probability denominator said probability numerator set to said similarity value times a first constant and said probability denominator set to the quantity of a second constant times said time between diagnosis value plus one (Ziegele: [0032], i.e. the constants both equal 1. The Examiner notes that probability calculation is old and, applying a variety of well-developed equations.).

E. As per claim 7, Seare discloses a method for episode classification using a multitude of diagnosis records (Seare: col 21, lns 10-19), each of said multitude of diagnosis records including: diagnosis information; time of diagnoses information; and patient information (Seare: col 22, lns 8-27); including the steps of:

a. creating at least one diagnosis pair from said multitude of diagnosis records, each said diagnosis pair containing a unique combination of two diagnoses information (Seare: col 24, lns 18-21, i.e. index codes contain at least one pair of diagnoses information.);

b. for each said diagnosis pair, iteratively:

i. determining a co-occurrence value, said co-occurrence value being the number of unique patients for whom the two diagnoses contained in each of said diagnosis pairs occurred within a co-occurrence window;

and

ii. associating said co-occurrence value with each diagnosis information contained in said diagnosis pair (Seare: col 27, lns 15-27);

c. creating at least one patient group, each said patient group generated by grouping said diagnosis records having similar said patient information (Seare: col 24, lns 21-26, i.e. sorting patients by "qualifying ICD code" produces a patient group.);

and

d. for each said patient group, iteratively:

i. creating at least one diagnosis group, each said diagnosis group generated by grouping said diagnosis records having similar said diagnosis information (Seare: col 24, lns 26-33, i.e., patients grouped by undertaking "procedures related to a specific medical condition");

ii. for each said diagnosis group, iteratively adding a unique occurrence identifier to said diagnosis information for each said diagnosis record (Seare: col 24, lns 38-45, reads on “staging indicator”);

iii. creating at least one time between diagnosis pair from said diagnosis records in said diagnosis group, each said time between diagnosis pair containing a unique combination of two said diagnosis records (Seare: col 24, lns 60-66, time between diagnosis reads on “clear window”);

iv. for each said time between diagnosis pair, iteratively:

1. setting a time between diagnosis pair value for each said diagnosis pair equal to the absolute value of the difference between said time of diagnoses information from each said diagnosis record in said diagnosis group (Seare: col 24, ln 60 to col 25, ln 26);

2. setting a score numerator equal to said co-occurrence value having the same combination of diagnosis information as said time between diagnosis pair value (Seare: col 27, lns 15-27, reads on “adjustment factor”);

3. calculating a score for said diagnosis pair by dividing said score numerator by said time between diagnosis pair value (The Examiner notes that the arithmetic process of division is well known);

and

4. associating said score to said diagnosis pair (Seare: col 27, lns 15-27);

v. setting a minimum score value equal to the minimum said score from the set of said scores associated to each of said diagnosis pairs in said patient group;

vi. setting a maximum score value equal to the maximum said score from the set of said scores associated to each of said diagnosis pairs in said patient group;

vii. setting a difference score value equal to difference of said maximum score value and said minimum score value (for steps v-vii, see Seare: col 27, ln 44 to col 28, ln 3, i.e. maximum and minimum scores provide the

limits of the recited "defined statistical criteria"; difference reads on "variance");

viii. for each said diagnosis pair, iteratively:

1. setting a standardized score numerator value equal to said minimum score minus said score associated to said time between diagnosis pair;

2. setting a standardized score equal to said standardized score numerator divided by said difference score value; and

3. associating said standardized score to said diagnosis pair (for steps viii 1-3, the Examiner notes that the statistical procedure of standardizing scores is well known. Also see Seare: col 6, ln 15 which identifies CPT codes as "standard," and note that the CPT and codes drive the scoring system of the reference invention.);

and

ix. classifying each said diagnosis information into at least one episode using said standardized score (Seare: col 25, lns 38-43).

F. As per claim 8, Seare discloses a method according to claim 7 wherein said step of classifying each said diagnosis information into at least one episode includes the steps of:

a. flagging each of said diagnosis information in said patient group for analysis (Seare: col 22, lns 10-12);

and

b. until all diagnosis information in said patient group is analyzed, iteratively:

i. combining two of said diagnosis information in said patient group flagged for analysis which have the maximum said standardized scores not exceeding a preset cutoff into an episode record (Seare: col 25, lns 29 - 62);

ii. creating a new diagnosis information, said new diagnosis information representing said diagnosis information in said episode record;

iii. calculating a new standardized score for said new diagnosis information by averaging the standardized score associated with each of

said diagnosis information in said episode record (for steps b ii-iii, see Seare: col 25, ln 65 to col 26, ln 6);

and

iv. de-flagging said diagnosis information in said episode record for further analysis (Seare: col 26, 12-13).

Response to Arguments

6. Applicant's arguments in the response filed 09/19/2007 have been fully considered but they are not persuasive. Beginning on page 8 of the response, in the heading of section IIB, Applicant indicates the combined teachings of the Seare, Ziegele, and Lockwood teach away from the recitations of independent claims 1 and 7, then provides six sub-sections containing arguments Applicant apparently feels support this assertion. The arguments in each subsection will be addressed in turn.

A. In subsection B1, Applicant asserts that the term "episodes of care" differ in meaning between the current invention and the applied prior art. In response, the Examiner first notes that the phrase “episode of care” is not recited in the claims, thus the relevance of this line of argument is not clear.

Applicant further states that “While…the prior art teaches the use of healthcare services for episodes of care, Applicants’ present invention teaches away from the use

of healthcare services for episodes of care." In response, the Examiner rejects this assertion, and points out that one need look no further than the language of claim 1 for example, which recites inclusion of "diagnosis information" and "patient information" in each of a "multitude of diagnosis records." Clearly this claim pertains to an "episode" related to the provision of healthcare services, such as providing a diagnosis. Applicant should further note that the term "teaches away" is normally reserved for arguing the relevance of the teachings of a reference as applied to a claim, not the other way around. As long as the reference teaches the recited feature or features of a claim to which it is applied, it is not relevant what an invention may imply with respect to the reference.

Applicant also points to paragraph [0025] in the specification, apparently to provide a definition of "episode of care" contrary to the plain meaning of the term. In response, the Examiner notes that the passage begins with "An episode of care **may be** defined as…" The Examiner points out that this conditional language appears intended to merely provide an example, and does not support the assertion that the specification strictly defines this term so as to preclude interpreting it as per its customary meaning in the art.

Finally, the Examiner notes that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is suggested that consideration be given to amending the claim language so as to more specifically limit the material Applicant is attempting to claim.

B. In subsection B2, Applicant appears to argue that the Ziegele reference does not teach the features of claim 1 which recites

> "a probability analyzer for performing probability calculations, each of said probability calculations capable of generating a probability value using at least two of said multitude of diagnosis records as input entries, said probability value representing the probability that said input entries belong to a single episode;

because Ziegele incorporates prescription data into the probability, whereas the current invention does not, and because diagnostic data are from different episodes. In response, the Examiner points to Ziegele: [0014] which recites "…links between a **plurality of diagnostic information records** and a plurality of prescription information records…" which are used for "…determining one or more…probabilities…" The Examiner notes that this meets the claim limitation of "…using at least two of said multitude of diagnosis records as input entries…"

We have already seen that Seare teaches statistical analysis concerning the determination of a valid episode (Seare: col 25, lns 28-63; Figs 2-5; col 28, lns 61-64, "...comparison of a health care provider's utilization of...ICD-9 codes in a specific episode of care..."), and one of ordinary skill in the art of medical record analysis would have found it obvious to apply the probability calculator of Ziegele to the problem of

episode determination addressed by Seare (Seare: col 23, lns 1-5) to more fully analyze treatment utilization patterns (Seare: col 1, lns 20-24).

C In subsection B3, Applicant revisits the argument addressed in subsection 1, this time applying it to the Lockwood reference. The Examiner refers Applicant to the above section for the response. Again the assertion that the current claims do not pertain to healthcare services is rejected, and it is reiterated that since no attempt to provide amendments to more properly define or limit the claimed material is made, perhaps this should be considered moving forward.

D. In subsection B4, Applicant argues that Ziegele does not teach pairwise analysis of diagnosis records. As support for this argument, Applicant relies largely on unclaimed suggestive material from the specification. In response and to reiterate, it is not permissible for the Examiner to read suggestive, non-definitional material from the specification into the claims. The Examiner notes that Seare teaches pairwise comparison of diagnoses (Seare: col 19, lns 54-58; col 20, lns 8-10; col 24, lns 38-40; col 28, lns 61-64, "...comparison of a health care provider's utilization of...ICD-9 codes in a specific episode of care..."). Ziegele, as noted above, teaches a probability calculator, which also operates on pairwise data (Ziegele: [0079]-[0080]) which includes diagnoses pairs. Combining the teachings would have been obvious for the reasons previously provided.

E. In subsection B5, Applicant, apparently referring to claim 6, argues that Ziegele does not teach a probability numerator and denominator as claimed. The substance of the argument is as in the preceding arguments, i.e. that the specification describes the current invention differently than the references, thus the substance of the response to this general argument is as presented previously. Regarding claim 6, the Examiner will further note that Seare teaches a similarity value (Seare: col 7, lns 35-64, i.e. "index code"); as well as a time between diagnostic value (Seare: col 24, ln 60 to col 25, ln 26, i.e. a "clear window" is the minimum time between similar diagnoses to distinguish an episode). Seare also teaches various ratios associated with these parameters. For instance Seare: col 11, lns 49-50 teaches a "duration parameter" which is a projected length of an episode (note that the units of this would be time/episode). Seare further teaches processing a relationship that shows episodes of an index code over a period of time (Seare: col 21, lns 62-67). Note that the frequency of episodes associated with an index code could also be considered a similarity value, and that the units of the foregoing ratio would be episodes/time, the same units in the "probability calculation" of claim 6, where the constants are set to 1. Ziegele adds the formality of a calculator for calculating these ratios as probabilities.

F. In subsection B6, Applicant makes an argument similar to the argument presented in subsection B4, i.e. that Seare (as opposed to Ziegele) does not teach processing claim records in pairs. In response, the Examiner notes that Seare teaches pairwise comparison of diagnoses (Seare: col 19, lns 54-58; col 20, lns 8-10; col 24, lns

38-40; col 28, lns 61-64, "...comparison of a health care provider's utilization of...ICD-9 codes in a specific episode of care..."), and Ziegele adds the feature of a calculator for calculating probabilities of pairwise frequencies of factors, such as diagnoses, associated with medical records. Applicant must recognize that it is the combination of the references that teaches all the features of the claim. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

G. As a final comment, in the heading of section IIB of the response, the Examiner notes that Applicant makes the broad assertion that the combination of Seare, Ziegele, and Lockwood teaches away from independent claims 1 and 7. The Examiner wishes to call attention to the difference between “not addressing” and “teaching away.” Speaking generally, while references may not address claimed features, not addressing is different than "teaching away" as defined by the Courts. The Courts have stated that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Applicant." Tex Air, Inc. v. Denso Mfg. Mich. Inc., 192 F.3d 1353, 1360, 52 YSPQ2d, 1298 (Fed. Cir. 1999). In the instant case, Applicant did not actually appear to attempt to argue that the references teach away in any of the points discussed above in paragraphs 6A to 6F, and the Examiner presumes that perhaps this was not the legal construct Applicant meant to invoke in the heading of section IIB of the response.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a system for tracking and measuring use of healthcare resources for episodes of illnesses of varying length.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN A. GOTTSCHALK whose telephone number is (571)272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Dixon can be reached on (571) 272-6803. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. A. G./
Examiner, Art Unit 3696

/James P Trammell/
Supervisory Patent Examiner, Art Unit 3694